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**septodont**

# Comprehensive Compliance Plan

## Septodont (North America)

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## **SEPTODONT (North America) COMPREHENSIVE COMPLIANCE PROGRAM**

Septodont (North America) (“Septodont”) is committed to implementing and maintaining an effective Comprehensive Compliance Program consistent with the Compliance Program Guidance for Pharmaceutical Manufacturers published by the Office of Inspector General (“OIG”), U.S. Department of Health and Human Services and the PhRMA Code on Interactions with Healthcare Professionals.

Septodont seeks to comply with the California Health and Safety Code (Section 119400 through 119402), which requires pharmaceutical and medical device companies to establish a Comprehensive Compliance Program. Septodont is also committed to complying with all applicable federal and state statutes and regulations.

Our Compliance Program was established by the Company’s Senior Management to ensure that our commitment to the highest standards of corporate ethics and conduct is clearly defined and comprehensive.

The Compliance Program reinforces our intention of ensuring that our interactions with healthcare providers are professional exchanges designed to benefit the patients and to enhance the practice of medicine. Septodont’s Compliance Program is based on the principle that a healthcare professional’s care of patients should be based, and should be perceived to be based, solely on each patient’s medical needs and the healthcare provider’s medical knowledge and experience. Further, in the context of its business activities and interactions, Septodont also seeks to ensure that fraud or abuse of the healthcare system is not tolerated. This document will serve to outline the measures that Septodont has undertaken to prevent and detect violations of law or company policy with respect to the interaction of our employees with the healthcare community, as well as with other defined and applicable regulatory standards.

An effective Comprehensive Compliance Program must be dynamic and responsive to new developments. Septodont will make conforming changes to its Program within six months of any update or revision to the OIG Compliance Program Guidance for Pharmaceutical Manufacturers or the PhRMA Code on Interactions with Healthcare Professionals or any applicable federal or state laws. We expect to review our Compliance Program yearly and to enhance it over time to meet our evolving compliance needs.

The essential elements of our Comprehensive Compliance Program are listed below:

## 1. Written Standards of Conduct/Policies & Procedures

### Standards of Conduct

Our Standards of Conduct are defined in numerous different written procedures throughout the company, including policies and procedures written by Human Resources, Finance, Quality, Sales and Marketing. Below outlines the principles upon which the various policies and procedures defined our Standards of Conduct. We have strived to ensure that no conflict exists between this document and our Standards of Conduct; and if any discrepancies are identified they will be resolved promptly to ensure compliance with the published regulations.

Every employee and affiliate of Septodont must recognize that he or she has assumed a number of ethical and professional responsibilities; and therefore, as such must follow the Standards of Conduct and report any violations of the Standards of Conduct.

A violation of a Standard of Conduct is a serious matter. Under appropriate circumstances, and after proper procedures have been followed, employees may be subject to discipline, up to and including termination, for violations of the Standards of Conduct.

#### A. Conduct of Septodont Business in a Legal and Ethical Manner

Septodont expects that all officers, employees and agents will:

- 1) Understand applicable laws, rules, and the Septodont policies or procedures which describe specific Standards of Conduct to the degree needed for them to carry out their responsibilities in accordance with those laws, Standards, and policies, and also to identify situation where other individuals may put Septodont at risk of violating those regulations.
- 2) Not commit or tolerate any conduct that may put Septodont at risk of violating the law or the company's ethical principles and Standards of Conduct.
- 3) Promptly contact Septodont's Compliance Officer whenever there is a question as to whether or not particular conduct violates the law or a Septodont Standard or policy.
- 4) Attend any Septodont-sponsored compliance training, as it relates to job functions.
- 5) Report to the Compliance Officer any pending criminal investigations involving health care fraud or any pending proceeding that could result in them being excluded from pharmaceutical sales/marketing activities.
- 6) Report violations of Standards of Conduct to the Compliance Officer.

#### B. Conflicts of Interest

Employees must avoid any investment, interest, activity or association that interferes, or might interfere with, their obligation to perform responsibilities in the best interests of Septodont.

### **C. Protection of Confidential Information**

The disclosure of confidential information regarding Septodont business or scientific operations, whether intentional or accidental, may adversely affect the financial stability and competitive position of Septodont as well as the job security of employees.

Employees shall not, without the written consent of Senior Management, during the term of employment or thereafter, use, directly or indirectly, for the personal benefit of themselves or others, or disclose to others, any confidential information of Septodont or of other entities obtained during the course of employment at Septodont.

Employees shall not seek or accept information designated as confidential in an illegal or unethical manner, and if information is offered or given that is reasonably viewed as having been obtained through illegal or unethical means, or even accidentally, the employee shall immediately report the matter to the Compliance Officer.

### **D. Compliance with Employment Laws**

It is the policy of Septodont to comply with employment laws, on both a local and Federal level. Septodont will provide employment opportunities without regard to race, religion, color, national origin, sex, age, ancestry, citizenship, veteran status, marital status, sexual orientation or disability, or any other reason prohibited by law. Decisions as to hiring, promotion and other aspects of the employment relationship are based solely upon job-related qualifications.

Septodont also prohibits sexual harassment, as well as harassment based on any of the other characteristics listed above, and will take appropriate action to eliminate prohibited harassment and remedy the effects of such harassment.

### **E. Compliance with the Law**

Septodont will operate all aspects of its business in compliance with all applicable Federal, State and Local laws and regulations, including for example, but not limited to Healthcare Fraud and Abuse Laws, the Food and Drug Act and Regulations, the federal Anti-Kickback Statue and Anti-Trust Legislation.

All government agents will be treated with respect. Any inquiry from a government agent outside the normal course of ministerial interactions for purposes of compliance with mandatory reporting requirements will be referred to the Compliance Officer and /or the President. In no event will any employee be prohibited from speaking voluntarily with a government agent engaged in an investigation or an enforcement action, although they may be advised that they are not obligated to speak with an agent

### **F. Compliance with Industry Standards**

Septodont offers to the marketplace a diverse and dynamic range of innovative products and solutions, including pharmaceuticals, medical devices, dental materials and other items that support and assist the healthcare practitioner, with their primary market being those individuals engaged within the practice of dentistry. As such, the activities of the business

frequently cover a broad scope of interactions related to its full range of product offerings. Such activities include both direct and indirect support of educational forums / speakers and other training / detailing activities, routine interactions for feedback and/or education of individual practitioners in the dental community at large or key opinion leaders, and extending to ethical business relationships with group practices. Regarding promotions or premiums associated with dental market trade shows and related events, these will be offered in a non-exclusive manner, which is consistent with applicable standards established by the conference sponsor or the body responsible for the educational activity. Within this context of the dental community at large Septodont's policy is to endorse the intentions as described in the PhRMA guidance outlining appropriate conduct for direct interaction between our employees and the healthcare practitioner as reiterated in the opening paragraphs of this document.

Septodont has based its Compliance Program on the recommendations included in the OIG's Compliance Guidance for Pharmaceutical Manufacturers and the PhRMA Code on Interactions with Health Professionals. A copy of the PhRMA Code may be viewed and downloaded at: <http://www.phrma.org/code-on-interactions-with-healthcare-professionals>.

Although the PhRMA Code does not, by its terms, apply to direct sales and marketing interactions with health care institutions and businesses (e.g. dental schools, wholesalers and distributors) or with indirect customers (e.g., health plans and their pharmacy benefits managers), Septodont, to the extent practicable, also will model its interactions with these customers according to our Standards of Conduct.

#### **G. Gifts and Entertainment**

Employees shall not seek, accept, offer, promise or give any payment, fees, loans, services or gifts from or to any person or firm as a condition or result of doing business with Septodont.

Items may be given when appropriate to licensed health care professionals, medical or dental students, or members of a drug formulary committee as long as each individual item is consistent the PhRMA Code; for example, items which generally support patient education or safety, or are associated with the normal conduct of business transactions such as sales/discounts, and which are not intended in any way to influence the free choice of the healthcare practitioner in choosing the most appropriate treatment option for their patient, or to otherwise influence that individual toward abuse or fraud related to their individual business, regulatory or ethical responsibilities.

In accordance with the California Law, which requires each pharmaceutical company to establish limits on gifts, promotional materials or items or activities that the company may provide to individual healthcare practitioners, Septodont has established that the value of each individual item does not exceed \$100, and the aggregate annual maximum for individual healthcare practitioners will not exceed \$3,000. Exclusions to this figure are described in the California legislation, and include for example, fees for services or educational support that is offered consistent with the guidance of the PhRMA Code.

Septodont also recognizes that some other States have more stringent State regulations than their counterparts when it comes to gifts and expenditures made to HCPs; and therefore, we intend to fully comply with such applicable State regulations.

Furthermore, Septodont is committed to declare all transfers of value in accordance with the Patient Protection and Affordable Care Act (§6002).

#### **H. Maintenance of the Accuracy and Integrity of Books and Records**

Septodont complies with the applicable standards and requirements for financial reporting.

#### **I. Appropriate Use of Electronic Media**

Septodont provides access to and use of electronic mail, voicemail, the Internet and other electronic media for business purposes. Septodont employees will comply with usage policies, and will not use electronic media for any purposes that violate federal, state or local laws.

#### **J. Policies Relating to Document Retention and Destruction**

Septodont employees will comply with the defined Document Retention procedure and will retain those documents that it is required to retain in order to comply with pertinent laws and regulations and that are needed for its daily operations. Documents will be retained long enough to satisfy specific legal requirements. Where documents are no longer required to be maintained by law or by legitimate business needs, they may be destroyed.

Any employee who has a question about what constitutes proper conduct is able to consult the Compliance Officer for guidance. This contact may be made confidentially. Our Compliance Officer will take the appropriate steps to investigate a question or a complaint. The Compliance Officer is responsible for answering questions about the Standards of Conduct and any Policies and Procedures that expand upon the Standards and for resolving disputed interpretations or otherwise instituting corrective action if required. You should have no hesitation whatsoever in consulting the Compliance Officer if you believe it is necessary to do so.

## **2. The Compliance Officer**

Our Compliance Officer, Eric Penrose Vice President of Quality, is responsible for the implementation, operation, and monitoring of the Septodont Comprehensive Compliance Program. He can normally be reached on his direct line at the Septodont Cambridge facility, telephone 519 629 0154 (equipped with voice mail). Many of the principal elements of the Compliance Program are under the direction and supervision of the Compliance Officer. The Compliance Officer reports to Mr. Kent Chiu, President of Septodont, Inc., and, when necessary has direct access to the Board of Directors.

## The Compliance Officer's duties include:

### A. Design and Coordination of Compliance Training

The Compliance Officer is responsible for the development and coordination of new hire compliance training, annual compliance training and periodic refresher training for Septodont managers, employees and independent affiliates who represent Septodont. Participation in annual compliance training will be mandatory. The Compliance Officer will create or identify appropriate programs for new and existing personnel. The focus of the initial compliance training will be the Comprehensive Compliance Program in general as well as the applicable Federal and State laws and regulations that apply to Septodont operations. When an area of perceived compliance risk involves specialized issues not of general concern to the entire employee population, the Compliance Officer may direct certain employees or affiliates to attend appropriate continuing education courses offered by commercial conference organizers or government agencies. All participants will be required to sign an attendance sheet at each internal training session that is conducted or certify attendance at external training sessions.

Training may be presented in a variety of ways. In-person meetings, video presentations, web-based training programs, and outside seminars are all acceptable training approaches. For certain situations, the Compliance Officer may also elect to require self-training through the review of documents and the completion of a certification that the materials have been read. Regardless of the medium used for training, the Compliance Officer maintains an open-door policy and routinely will be available to answer questions and clarify instructions.

### B. Establishment of Internal Lines of Communication

It is the responsibility of the Compliance Officer to foster dialogue between management and employees. The Compliance Officer must ensure that all employees and contractors know who to turn to for a meaningful response to a compliance or standard of conduct question and how to report suspected violations of the company's Standards of Conduct or applicable federal or state laws.

Employees, contractors or other persons may make a report of violations of the Standards of Conduct or applicable federal or state laws by calling the Compliance Officer. This contact may be made confidentially. The report will be evaluated by the Compliance Officer to determine whether an investigation is warranted. Alternatively, a person may report their information by letter or email to the Compliance Officer discussing their concerns. Written reports will be treated with the same degree of confidentiality as oral reports. Employees should be assured that retaliation for filing a report of a suspected violation in good faith is absolutely prohibited, even if the report is not found to be accurate or it is determined that no violation of the Standards of Conduct or applicable laws occurred.

It is the responsibility of the Compliance Officer to maintain contact with Legal Counsel and other sources in order to keep Septodont aware of new regulatory and legal developments affecting its operations, particularly those relating to sales and marketing, and various required reporting obligations. It is also the duty of the Compliance Officer to disseminate to

the appropriate Septodont personnel information concerning regulatory and legal developments. Normally this will be accomplished through memoranda or circulated copies of the pertinent regulations, laws, or other documents. The Compliance Officer, however, should be prepared to conduct or arrange for compliance workshops if extensive and complicated changes must be implemented and new procedures developed as a consequence of any statutory or regulatory development.

The Standards of Conduct or the Compliance Program will be updated if necessary based on questions or concerns or reported violations received.

### **C. Auditing and Compliance Monitoring**

The Compliance Officer will perform periodic audits and reviews of certain facets of Septodont operations, including its sales and marketing practices. The nature of these reviews as well as the extent and frequency of our monitoring and auditing activities will vary depending upon perceived regulatory risk, new regulatory requirements, changes in business practices, and other considerations. We expect our routine evaluation of enforcement developments coupled with our periodic assessments of our operations to result in the identification of new and emerging risk areas that will be subsequently addressed through enhancements to our Compliance Program.

This Comprehensive Compliance Program is intended to adapt to changes in the law and to Septodont operation and experiences. The Program itself will be reviewed regularly to assess how it is working. As part of this process, the Compliance Officer will prepare an annual report for the Senior Executive Committee that describes the general compliance efforts that Septodont has undertaken. This report will also identify any changes that are needed to be implemented to ensure that the Program is functioning effectively. The annual report will incorporate substantive learning about risk areas and risk management learned from periodic audits and reviews, complaint-driven investigations, employee and contractor questions, exit interviews and the like.

If anything in the report identifies areas of possible non-compliance, the Compliance Officer will report that fact to Senior Executive Committee.

### **D. Investigation of Reports Regarding Compliance with the Standards of Conduct**

The Compliance Officer is responsible for reviewing, assessing and, as appropriate, investigating reports of possible misconduct from Septodont employees, independent contractors or others. If the Compliance Officer concludes, based upon the initial review of a report, that the report contains allegations that should be investigated further, the Compliance Officer will initiate an investigation. The Compliance Officer is responsible for conducting the expeditious investigation of any credible report that alleges a violation of Septodont's Standards of Conduct or applicable law. If necessary, the Compliance Officer may request assistance from Legal Counsel in completing any of these responsibilities.

Promptly at the conclusion of any investigation, the Compliance Officer will draft a report of findings and recommendations. This report will be forwarded for review by Septodont Senior Management or if Senior Management is implicated in any wrongdoing, to the Board of Directors.

The Compliance Officer will maintain a detailed log of investigated reports of actual and possible violations of compliance policies and applicable federal or state laws – stating the nature of the investigation, outcome, corrective actions and disciplinary action taken, if applicable.

### **E. Involvement in Disciplinary Actions**

Coordination and oversight of the disciplinary process is normally a function organized through the Human Resources team. However, for any officer, employee, or contractor of Septodont who is found to have violated the Standards of Conduct the Compliance Officer may be involved to ensure the individual is disciplined in an appropriate, measured, and consistent fashion. The Senior Executive Committee shall review all significant decisions on an annual basis to ensure that this standard has been met.

It shall be the Compliance Officer's responsibility working in cooperation with Human Resources to establish an appropriate schedule of penalties, including possible termination, which shall be applicable to violations of this Comprehensive Compliance Program. The Compliance Officer also will take steps to ensure that the applicable disciplinary guidelines are well publicized throughout the organization.

## **3. Effective Training and Education**

Septodont is committed to developing and conducting effective compliancy training program for its employees, contractors and sales force under the direction of the Compliance Officer. We are committed to ensuring that all levels of personnel are aware of our compliance program, Standards of Conduct and applicable federal and state laws.

Septodont will regularly review and update its training programs and materials to ensure that they reflect changes to Septodont operations, its Comprehensive Compliance Program, the OIG Compliance Program Guidance for Pharmaceutical Manufacturers, the PhRMA Code, and applicable law. Septodont may also identify additional areas of training on an as-needed basis.

## **4. Internal Communication**

Septodont operates under an open door policy and employees can freely approach the Compliance Officer with questions or concerns they may have or report non-compliance issues. In order to encourage communication between employees and the Compliance Officer, Septodont has confidentiality and non-retaliation policies in place; therefore, employees can report matters of concern confidentially and without fear of retribution.

## 5. Internal Auditing and Monitoring

In order to monitor the effectiveness of the Compliance Program, periodic audits are conducted by the Compliance Officer to identify if there are any changes that need to be implemented, problem areas or areas that need improvement.

## 6. Enforcing Standards Through Disciplinary Actions

Septodont acknowledges that different categories of conduct may exist (i.e., simple negligence, gross negligence, or willful misconduct) and this will be taken into consideration when determining the appropriate discipline. Certain offenses may justify immediate termination of employment:

- 1) Violation of any Federal or State criminal statute;
- 2) Failure to report conduct by an employee, contractor, officer, or director that a reasonable person under the circumstances should have known was a violation of law;
- 3) Failure to report a violation of the Standards of Conduct by any employee, contractor, officer, or director that a reasonable person under the circumstances should have known violated the Standards;
- 4) Knowingly or willfully obstructing any government investigation or audit.

An employee or independent contractor whose conduct would otherwise justify termination may have a lesser discipline imposed depending upon (a) whether the employee or independent contractor reported his or her own violation; (b) whether the report constitutes Septodont's first notice of the violation and the employee's or contractor's involvement and (c) whether the employee or independent contractor has provided full and complete cooperation during the Compliance Officer's investigation of the violation.

All managers and supervisors are encouraged to take appropriate action to identify any misconduct committed by employees or others whom they supervise. Managers may be subject to discipline for failure to detect compliance violations that occur to the extent that the manager is negligent in this duty. If a manager or supervisor, through negligence, carelessness, or inattention, facilitates or prolongs misconduct, then an appropriate disciplinary action based on the seriousness of the offense will be imposed.

## 7. Responding to Detected Problems and Implementing Corrective Action Initiatives

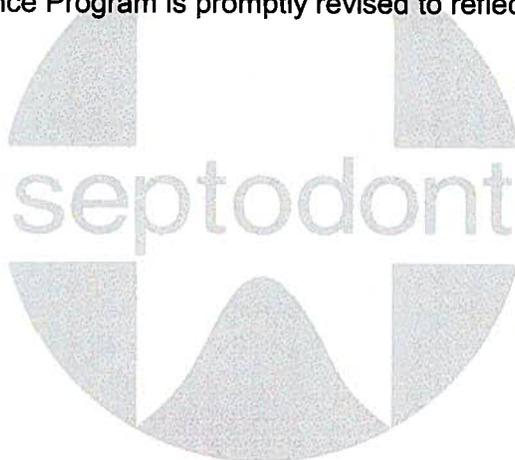
Reports of actual and suspected violations of compliance policies or applicable laws will be documented and investigated promptly. If an investigation determines that a violation has occurred then a corrective action plan will be put in place to remediate the violation and if necessary, appropriate federal or state authorities will be notified.



## 8. Other Matters

As a worldwide leader in local dental anesthetics, we are recognized globally; and therefore, interact with international regulatory bodies, customers and institutions. We strive to respect all cultures, customs and traditions.

Operation of the Septodont Comprehensive Compliance Program increases the likelihood of preventing unlawful and unethical behavior. However, even an effective Compliance Program may not prevent all violations of applicable laws. As such, our Compliance Program requires Septodont to respond promptly to potential violations of our Standards of Conduct or of applicable law, take appropriate disciplinary action, assess whether the violation is in part due to gaps in our policies, practices, or internal controls, and take action to prevent future violations. In addition to assessing the Compliance Program annually and making recommendations to the Senior Executive Committee for needed responses to concerns, the Compliance Officer coordinates these tasks in an ongoing manner throughout the year and ensures that the Compliance Program is promptly revised to reflect changes in the law or industry standards.



A handwritten signature in black ink, appearing to read "Eric Penrose", is written over a horizontal line.

Eric Penrose, Compliance Officer

2013-12-12  
Date